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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/996,569      | 11/30/2001  | Daniel R. Soppet     | PF201D2             | 3798             |

22195 7590 05/19/2004

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EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/996,569

**Applicant(s)**

SOPPET ET AL.

**Examiner**

Lorraine Spector, Ph.D.

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/11/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Part III: Detailed Office Action**

**Formal Matters:**

The new title of the invention is acknowledged.

The objection to claims 31, 32, 53, 54, 68, 69, 90, 91, 99 and 100 under 37 CFR 1.75(c) is withdrawn in view of applicants arguments in the paper filed 3/11/2004.

The objection to claim 10 under 37 CFR 1.75(c) is moot in view of the cancellation of the claim.

The amendment to the abstract is acknowledged, and overcomes the objection to same.

Applicant is advised that should claims 25, 42, 48, 62, 79 or 85 be found allowable, claims 26, 44, 49, 63, 81, and 86, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicants amendment to overcome the previous provisional objection to duplicate claims necessitates the new provisional objection.

The formal drawings submitted 11/30/2001, as pointed out by applicants, are acceptable.

The rejection of claim 10 under 35 U.S.C. §101 is moot in view of the cancellation of the claim.

Applicants statement in the paper filed 3/11/2004 at page 28-29 is sufficient to overcome the rejection of claims 58-94 under 35 U.S.C. §112, first paragraph requiring a biological deposit.

**Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 50, 64 and 87 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 27, 50, 64 and 87 recite that the protein to which the claimed antibodies bind is glycosylated. As there is no disclosure of the glycosylation state of the protein as it occurs in nature, and further, as proteins may be artificially glycosylated, to the extent that the glycosylation is other than that which would occur in nature, and further, to the extent that such glycosylation would either create epitopes not found in the disclosed protein or hide epitopes, there is no written description of the epitopes so created or affected, and hence of antibodies that bind specifically to the protein in a glycosylated state. It is noted that there is no lack of adequate written description of the claimed antibodies as they would be raised to a protein produced in a specific host cell, or as isolated from nature. However, the instant claims specifically recite that the antibodies bind to the protein in glycosylated form, and no such form has been disclosed. To the extent that the claimed antibodies differ in scope from those, for example, of claim 21, there is no written description of such antibodies.

Applicants traversal in the paper filed 3/11/2004 has been fully considered but is not deemed persuasive. Applicants argue that production of such antibodies would be routine. This argument has been fully considered but is not deemed persuasive because this rejection is not for lack of enablement, but rather for lack of written description. It remains that the specification as originally filed evinces no conception of antibodies that differentially bind to the protein in any glycosylated state, natural or otherwise, as compared to non-glycosylated protein.

The rejection on the basis that the “mature” form of the polypeptide was not described is withdrawn because, although the mature form has not specifically been disclosed, the majority of antibodies to SEQ ID NO: 2 would bind to such, as such would be expected to comprise all but 21-24 residues of that sequence. Applicants argument that the “mature” form is *inherent* to the protein sequence was specifically *not* persuasive, as the nature of the “mature” form depends upon the particular cell that produces the protein, and not strictly upon the protein sequence.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 95-100 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 95 is indefinite because (a) there is no nexus between the recited polynucleotide and the PTH receptor expressed on the cells. Applicants traversal in the paper filed 3/11/2004 that there is a nexus has been fully considered but is not deemed persuasive. A nexus between the nucleic acid and the regulatory sequences does not address the issue. It remains that the claim does not indicate that the antibody binds to the protein encoded by SEQ ID NO: 2.

The remaining claims are indefinite for depending from an indefinite claim.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21-27, 29, 31-50, 53-64, 66, 68-79, 81-87, 90-100 remain rejected under 35 U.S.C. 102(e) as being anticipated by Segre et al., U.S. Patent Number 5,840,853. This rejection is based upon the effective filing date of the patent, which is *at least* 4/6/1992 for reasons of record in the previous office action, mailed 12/11/2003.

Applicants traversal of this rejection in the paper filed 3/11/2004 has been fully considered but is not deemed persuasive. Applicants argue that the recitation of "specifically binds" in the claims circumscribes any cross-reactive antibodies. This argument has been fully considered but is not deemed persuasive because the sequence identity between Segre's protein and applicants is such that proteins to Segre's protein would be expected to bind *to the same amino acids* of applicants protein. Applicants' argument of the meaning of the term "specific binding" is contrary and repugnant to the art, and if persuasive, would lead to rejections under 35 U.S.C. §112, first and second paragraphs on the basis of lack of adequate written description, and indefiniteness, as the metes and bounds of such a claim would be uninterpretable in the absence of knowledge of all possible proteins that might cross react. The term is commonly accepted in the art as being specific to an epitope, as compared to non-specific binding. As the epitope of Segre's peptide would be the same as that of applicants protein, an antibody that specifically bound to the peptide of Segre would be expected to also specifically bind to the protein of SEQ ID NO: 2. Further, the specification provides no limiting definition of the term "specifically binds." It thus remains that antibodies Segre's SEQ ID NO: 7 would bind to larger proteins comprising that sequence, and the claims are anticipated by Segre et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30, 52, 67, 80, and 89 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Segre et al., U.S. Patent Number 5,840,853, in view of U.S. Patent Number 5,565,332 (Hoogenboom et al.), or in view of U.S. Patent Number 4,946,778 (Ladner et al. ) for reasons of record in the Office Action mailed 12/11/03. Applicants arguments in the paper filed 3/11/04 have been fully considered but are not deemed persuasive for reasons cited above.

Claims 28, 51, 65, and 88 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Segre et al., U.S. Patent Number 5,840,853, in view of U.S. Patent Number 5,298,419 (Masuho et al.) for reasons of record in the Office Action mailed 12/11/03. Applicants arguments in the paper filed 3/11/04 have been fully considered but are not deemed persuasive for reasons cited above.

**Advisory Information:**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

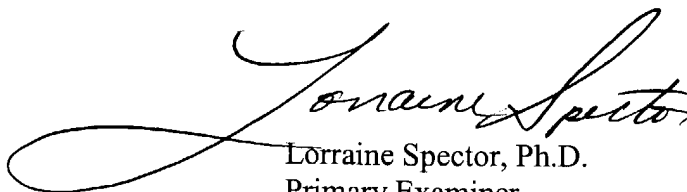
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. **Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.**

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, **Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.**

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.  
Primary Examiner